

Remarks

The Final Office Action mailed 16 August 2004 has been received and reviewed. No claims having been amended or added, the pending claims are claims 1-38. Reconsideration and withdrawal of the rejections are respectfully requested.

The 35 U.S.C. §102/103 Rejection

The Examiner rejected claims 1, 10-12, 15, 16, 18, 19, 22, 23, 30, and 36 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Rawlings et al. (U.S. Patent No. 5,409,472). Applicant respectfully traverses this rejection.

“[I]t is not uncommon that a ‘species’ may be patentable, that is, satisfy sections 101-103, notwithstanding a prior art ‘genus’ ” (e.g., *In re Ornitz*, 376 F.2d 330, 336, 153 USPQ 453, 458 (CCPA, 1967). Furthermore, “a prior genus which does not explicitly disclose a species does not anticipate a later claim to that species” (e.g., D. Chisum, Chisum on Patents, Volume 1, Release No. 94, §3.02[2][b] page 3, line 9 to page 4, line 2).

Rawlings et al. disclose a genus of wound dressings that includes, among the layers, a “polymeric foam absorbent layer” (e.g., abstract). Rawlings et al. further disclose a genus of polymers that can be used to make the foam layer. For example, Rawlings et al. disclose that “[a]pt foams may be polyurethane, carboxylated butadiene styrene rubber, polyacrylate or the like foam” (e.g., column 6, lines 58-59). Polymers in this genus may arguably be either hydrophilic or hydrophobic polymers.

However, Rawlings et al. provide no specific disclosure of a foam including a **hydrophobic** polymer. In contrast, Rawlings et al. disclose that the “foam is preferably a highly conformable **hydrophilic** foam” (e.g., column 6, lines 32-33, emphasis added). Further, Rawlings et al. disclose that “[f]avored **hydrophilic** polymer foams are **hydrophilic** polyurethane and especially those which are made of cross-linked **hydrophilic** polyurethane. Preferred foams can be made by reacting a **hydrophilic** isocyanate terminated polyether prepolymer with water” (e.g., column 7, lines 3-7, emphasis added). Finally, Rawlings et al. provide working examples

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only for a wound dressing with a foam with a **hydrophilic** polymer (e.g., Examples 1 and 3 and cited patent GB 2,188,055).

As such, Applicant respectfully submits that Rawlings et al. do not specifically exemplify or provide an enabling disclosure of the presently claimed species, i.e., a medical article including an absorbent, substantially nonswellable foam including a **hydrophobic** polymer. Thus, Rawlings et al. do not anticipate present claims 1, 10-12, 15, 16, 18, 19, 22, 23, 30, and 36. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102.

“The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)” (e.g., M.P.E.P. § 2144.08). Furthermore, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)” (e.g., M.P.E.P. § 2141.02, emphasis in original).

Applicant respectfully submits that Rawlings et al. provide no guidance for one of skill in the art to select, as a polymer for a foam in a medical article, a **hydrophobic** polymer, to arrive at an absorbent, substantially nonswellable foam as recited in the present claims. In fact, Rawlings et al. actually teach away from the presently claimed medical articles including foams that include **hydrophobic** polymers. For example, Rawlings et al. disclose that “[i]t is much preferred to use foams which are made of a polymer which is itself **hydrophilic**” (e.g., column 6, lines 62-65, emphasis added). Further, Rawlings et al. disclose that “[f]avored **hydrophilic** polymer foams are **hydrophilic** polyurethane and especially those which are made of cross-linked **hydrophilic** polyurethane” (e.g., column 7, lines 3-5, emphasis added). Thus, Rawlings et al. teach away from medical articles that include foams including **hydrophobic** polymers.

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Further, foams including *hydrophobic* polymers, as recited in the present claims, can offer useful properties. For example, in some embodiments, the foam "absorbs greater than 250% by weight aqueous saline solution when immersed in phosphate buffered saline containing 0.9 wt-% NaCl at 37°C for 30 minutes" (e.g., present claim 7). In other embodiments, the "substantially nonswellable foam increases in volume by no greater than about 10% following a 30-minute soaking in phosphate buffered saline at 37°C" (e.g., present claim 13). These properties are not specifically taught or suggested by Rawlings et al.

Moreover, medical articles or wound dressings that include foams including *hydrophobic* polymers, as recited in the present claims, can provide useful properties. For example, in some embodiments, such medical articles have "a dry moisture vapor transmission rate of less than about 2000 g/m²/24 hours at 38°C and 20% relative humidity" (e.g., present claim 2). In other embodiments, such medical articles have "a wet moisture vapor transmission rate of at least about 3000 g/m²/24 hours at 38°C and 20% relative humidity" (e.g., present claim 3). These properties are not specifically taught or suggested by Rawlings et al.

Despite Rawlings et al.'s lack of an enabling disclosure of the presently claimed species, i.e., a medical article including an absorbent, substantially nonswellable foam including a *hydrophobic* polymer, the Examiner asserted that "it is inherent that if the surfactant is placed on a foam to render it hydrophilic, *it must be hydrophobic*" (page 4, lines 10-11 of the Office Action mailed August 16, 2004; emphasis added). Applicant earnestly disagrees with the Examiner's assertion.

Rawlings et al. state that "foams may be made of hydrophilic materials per se or may be treated to render them hydrophilic, for example with surfactants" (column 6, lines 60-62). Although Rawlings et al. clearly disclose treating foams with surfactants to render them hydrophilic, Rawlings et al. is totally silent regarding whether the foam, before treatment with the surfactant, is hydrophilic, hydrophobic, or neither hydrophilic nor hydrophobic. In evaluating lack of disclosure regarding an obviousness rejection, the Court of Customs and Patent Appeals stated that "[s]ilence in a reference is hardly a proper substitute for an adequate disclosure of

facts from which a conclusion of obviousness may justifiably follow." (See *In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A 1966)).

Moreover, Applicant respectfully submits that one of skill in the art might treat a foam that is neither hydrophilic nor hydrophobic with a surfactant to render it hydrophilic. Similarly, one of skill in the art might treat a foam that is hydrophilic with a surfactant to render it more hydrophilic. Based on the above remarks, Applicant respectfully submits that it does not necessarily follow that the foam disclosed by Rawlings et al., before treatment with the surfactant, is hydrophobic. Thus, the Examiner's assertion that "it is inherent that if the surfactant is placed on a foam to render it hydrophilic, it must be hydrophobic," is not supported by the actual disclosure of Rawlings et al.

Further, the Examiner noted that "although Rawlings et al. prefer the use of hydrophilic foams, Rawlings et al. also disclose the use of foams made hydrophilic by the application of a surfactant thereto" (page 7, bottom three lines of the Office Action mailed August 16, 2004). The Examiner then asserted that "[t]hese foams are *inherently hydrophobic* and *inherently nonswellable*" (page 7, bottom two lines of the Office Action mailed August 16, 2004; emphasis added). Again, Applicant earnestly disagrees with the Examiner's assertion.

As discussed herein above, the Examiner's assertion that Rawlings et al. inherently disclose a hydrophobic foam is not supported by the actual disclosure of Rawlings et al. Further, Applicant respectfully disagrees with the Examiner's assertion that the foams disclosed by Rawlings et al. are *inherently nonswellable*. *See, for example*, the arguments presented by Applicant on pages 3-4 of the Amendment and Response submitted March 12, 2002; pages 4A-6A of the Amendment and Response submitted August 30, 2002; and pages 7-8 of the Amendment and Response submitted January 20, 2004, which are incorporated herein by reference. *See, also* the Declaration by Mary M. Swenson submitted March 26, 2002 and the Exhibits A and B submitted with the Amendment and Response on August 30, 2002. Applicant respectfully reminds the Examiner that "[e]vidence traversing rejections . . . must be considered by the examiner whenever present" (M.P.E.P. §716.01).

As such, Applicant respectfully submits that the present claims 1, 10-12, 15, 16, 18, 19, 22, 23, 30, and 36 are neither anticipated by nor obvious over Rawlings et al. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102 and/or 103.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 2-9, 13-14, 24-32, 34, 35, 37, and 38 under 35 U.S.C. §103(a) as being unpatentable over Rawlings et al. (U.S. Patent No. 5,409,472). Applicant respectfully traverses this rejection.

The deficiencies of Rawlings et al. have been discussed herein above in the remarks to the rejection of claims 1, 10-12, 15, 16, 18, 19, 22, 23, 30, and 36 under 35 U.S.C. §102/103. In brief, Rawlings et al. fail to disclose or suggest a medical article including an absorbent, substantially nonswellable foam including a *hydrophobic* polymer.

As such, Applicant respectfully submits that the present claims 2-9, 13-14, 24-32, 34, 35, and 37 (which depend directly or ultimately from claim 1 or claim 24), and claim 38 (which recites "an absorbent, substantially nonswellable foam comprising a hydrophobic polyurethane") are not obvious over Rawlings et al., for at least the reasons presented herein above. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

The Examiner also rejected claims 10, 17, 20, 21, 28, and 33 under 35 U.S.C. §103(a) as being unpatentable over Rawlings et al. (U.S. Patent No. 5,409,472) in view of Ward (U.S. Patent No. 5,000,172). Applicant respectfully traverses this rejection.

The deficiencies of Rawlings et al. have been discussed herein. Applicant respectfully submits that Ward, which relates "to a wound dressing system which includes a transparent or translucent layer having reference marks which are capable of being used to monitor the size of

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the wound" (column 1, lines 5-8), does not disclose subject matter that would correct the deficiencies of Rawlings et al. noted herein above.

Thus, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness of claims 10, 17, 20, 21, 28, and 33 under 35 U.S.C. §103. Applicant respectfully requests reconsideration and withdrawal of the rejection.

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Summary

It is respectfully submitted that all pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Mary M. SWENSON

By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228

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Date

By: Ann M. Mueting
Ann M. Mueting
Reg. No. 33,977
Direct Dial (612) 305-1217

CERTIFICATE UNDER 37 CFR §1.10:

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Date of Deposit: October 29, 2004

I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Rachel Gagliardi-Rosen
Name: Rachel Gagliardi-Rosen
